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TITLE: THE USE OF BONE REPAIR MATERIALS FOR MAXILLARY ALVEOLAR CLEFTS

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Principal Investigator's Signature Date

The objective of this study is to compare the standard of care for bone regeneration, the autogenous bone graft, to experimental materials consisting of a biodegradeable carrier and a bone inductive protein (BIP).

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The need for bone regeneration materials to correct traumatically-induced hard tissue deformities of the craniofacial skeleton, deformities secondary to ablative surgery, and congenital deformities is well documented. In this study, a previously described canine model with artificially created bilateral alveolar clefts is utilized to compare autologous iliac crest bone grafts to the bony defects, with bone inductive protein and a biodegradeable carrier, and biodegradeable carrier alone.

The bilateral alveolar clefts were first created. They were allowed to mature for several months to permit the development of an oronasal fistula lined with epithelium. The canines were then randomized into four treatment groups consisting of a control group (sham operation), autologous bone graft (iliac crest), bone inductive protein + biodegradeable carrier, and biodegradeable carrier alone and the clefts grafted. After allowing for osseous regeneration, the animals were sacrificed and the maxillae harvested. Photographs and radiographs were obtained. The bony specimens have been forwarded for processing prior to histological and histomorphometric evaluation.

No conclusions have been reached as the histological and histomorphometric evaluations are pending.